

REMARKS

Claims 1 through 15 are currently pending.

Rejection under 35 U.S.C. § 103

Claims 1 through 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Aoi et al. (hereinafter "Aoi") in view of Gans et al. (hereinafter "Gans") and Furia.

Specifically, the Office Action states that "Aoi teaches an enteral composition and teaches the composition may comprise preservatives such as p-hydroxybenzoic acid (i.e. parabens), salts of benzoic acid and salts of sorbic acids. Aoi, however, fails to teach the species and quantities recited in claim 1."

In order to anticipate a composition when a reference discloses multiple variables and combinations, the reference must describe the composition with enough detail such that the composition is in the possession of the public. In re Brown, 329 F. 2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Also, the reference must clearly and unequivocally disclose the composition or direct those skilled in the art to the composition without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the reference. In re Arkley, 455 F.2d 586, 587, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972). Additionally, under the obviousness standard, while it may be obvious to try to vary all parameters or try each of numerous possible choices, the reference must suggest the combination and selection of parameters for the composition. In re O'Farrell, 853 F.2d 894, 903, 7 U.S.P.Q.2d 1673, 1681 (Fed. Cir. 1988). The fact that parabens, salts of benzoic acid and salts of sorbic acids are recognized as preservatives does not give the public possession of the invention. Aoi is silent in teaching the particular type of and amount of parabens, salts of benzoic acid, and salts of sorbic acid. Not all compositions will have the same efficacy, too little of the composition can be ineffective where too much can be dangerous.

Now turning to the combination of Aoi with Gans, "Even if the teachings of a primary reference could be modified to arrive at the claimed subject matter, the modification is not obvious unless the prior art also suggests the desirability of such a modification." In re Laskowski, 10 U.S.P.Q.2d 1397, 1398 (Fed Cir. 1989). Further, "A reference that performs a step of a claimed process for a different purpose and does not recognize the problem solved in applicants' process does not render the process obvious." Ex parte Wisdom et al., 184 U.S.P.Q. 822 (POBA 1973).

The nutritional compositions disclosed in Gans are not complete feeding solutions. Gans teaches or suggests solutions that expressly exclude fat which is a macronutrient required for a complete feeding solution. In column 2, lines 47 through 58, Gans distinguishes its disclosed nutritional compositions from those of the prior art by the very fact that they lack triglycerides. Although Gans does teach some amounts and of parabens and salts of sorbic or benzoic, there

is no teaching to suggest that the same parameters would work with the addition of the fats. The addition of fats could modify the composition of Gans in a way that would cause failure of the preservative system or the formation of undesirable by-products. There is no teaching or suggestion in Gans that his formulation would be successful with the addition of fats.

Furia fails to teach or suggest the use of parabens in combination with salts of benzoic and sorbic acids in a nutritionally complete feeding solution. . The Applicants have surprisingly discovered that an alkyl paraben when used in combination with the salts of benzoic and sorbic acids results in an enhanced synergism when functioning as a preservative. As shown in Example 4 of the Specification, the Applicants have found that the inhibitory synergism resulting from a combination of propyl paraben, sodium benzoate and potassium sorbate was greater than any of them singly for *Candida albicans*, *Enterobacter cloacae*, *Staphylococcus aureus*, and *Lactobacillus delbrueckii*.

Further, Furia "does not recognize the problem solved in applicants' process" (Ex parte Wisdom et al., 184 U.S.P.Q. 822 (POBA 1973)) of prolonging the life of an enteral feeding tube.

Since Furia does not teach nor suggest the use of salts of benzoic acid with parabens, there is no suggestion or motivation to combine Furia with Aoi and no way to achieve the present invention as claimed.

Thus, because there is no motivation to combine Aoi, Gans and Furia, and because there's no reasonable expectation of success, then the Examiner has not set forth a *prima facie* case of obviousness thus rendering this rejection improper. The Applicants respectfully request that this rejection be withdrawn.

Claims 13 through 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gans in view of Aoi. Similar to the prior discussion for Claims 1 through 12, Applicants respectfully submit that a *prima facie* case of obviousness has also not been established. Although Gans does teach some amounts and of parabens and salts of sorbic or benzoic, there is no teaching to suggest that the same parameters would work with the addition of the fats.

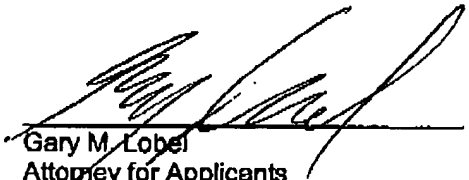
The ultimate legal conclusion of obviousness must be based on facts or records, not on the Examiner's unsupported allegation that a particular structural modification is "well known" and thus obvious. In re Wagner et al. 152 USPQ 552 (CCPA 1967) . "Examiner states that "it is notoriously well known that a higher water content in combination with protein and carbohydrate is more susceptible to microbial problems than one of lower water and higher fat. " Applicant respectfully disagrees. Further, the Examiner states that "if the preservative disclosed by Gans were effective for a higher water content solution, one would expect them to be just as effective in a lower water content/higher fat solution" The Applicant again respectfully disagrees. A change of water content or the addition of fats could modify the composition of Gans in a way that would cause failure of the preservative system or the formation of undesirable by-products. There is no teaching or suggestion in Gans that his formulation would be successful with the addition of fats or any change in water content

Thus, Applicants respectfully submits there is no motivation or suggestion to combine *Gans* with *Aoi* since the nutritional compositions taught or suggested in each reference is different from each other. Hence, Applicants respectfully request that this rejection be withdrawn.

Thus, in view of the foregoing arguments, Applicants respectfully request reconsideration of the present application. If a telephone interview would be of assistance in advancing the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7954


Gary M. Lobel
Attorney for Applicants
Reg. No. 51,155

Date: 31 January 2005